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SURGICAL INSTRUMENT SERVICE COMPANY, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC. *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counterclaimant.*	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **PLAINTIFF SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S OPPOSITION TO INTUITIVE'S MOTION TO EXCLUDE PHIL PHILLIPS' EXPERT OPINION TESTIMONY** Hearing: June 8, 2023 Time: 10:00 AM PT Courtroom: Courtroom 5, 17th Floor Judge: The Honorable Vince Chhabria Complaint Filed: May 10, 2021

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MEMORANDUM OF POINTS AND AUTHORITIES

I. FDA's regulatory definition of a "remanufacturer" is unclear and does not definitively compel SIS to obtain 510(k) clearance for its EndoWrist service operation; it is appropriate for Mr. Phillips, an expert in FDA operations and processes, to opine on this issue

A. Mr. Phillips' opinion is adequately explained based upon sufficient facts and data applied to this case.

One issue raised by Intuitive in this case is whether SIS was a "remanufacturer" required to obtain 510(k) clearance in order to engage in its planned commercial activities involving Intuitive's EndoWrist instruments. As explained in SIS's motion for summary judgment (Dkt. 127), FDA has repeatedly publicly acknowledged that the definition of "remanufacturer" is unclear and that it has not actively regulated these activities in the past. This is true despite years of OEMs lobbying FDA and multiple failed OEM attempts to resolve the issue, such as last year's "Clarifying Remanufacturing to Protect Patient Safety Act of 2022."

Mr. Phillips utilizes his decades of experience with FDA and extensive knowledge of FDA operating procedures and processes in context, not to resolve ultimate legal questions, but to assess the objective reasonableness of certain actions and statements of the parties. Specifically, assessing the objective reasonableness of SIS's not seeking 510(k) approval as a "remanufacturer" depends on understanding the context of FDA's regulations defining a "remanufacturer" and "remanufacturing." FDA's definition of a "remanufacturer" or "remanufacturing" is based, *inter alia,* on whether the activity at issue "significantly changes the finished device's performance or safety specifications, or intended use." 21 CFR § 820.3(w). Mr. Phillips opines that FDA regulations do not define, nor explain how one would determine when an act performed on a finished medical device "significantly changes the finished device's performance or safety specifications, or intended use." Lazerow Dec. Ex. 1 at ¶¶s 62-64, 66. Accordingly, Mr. Phillips opines that FDA regulations do not provide a clear standard for parties such as SIS to determine whether their operations "significantly change" the EndoWrist "performance or safety

specifications, or intended use." Id. Based on these undeniable facts, Mr. Phillips provides the following conclusion summarizing the analyses presented in his opening expert report:

> "If SIS had consulted with me at the time it was setting up its 'servicing' operation in regard to Intuitive Surgical's EndoWrists and asked whether the company was subject to active FDA regulation (specifically, registration and listing, premarket notification/510(k) requirements, and the QSR), I would have advised SIS that it was not. Based on the information that I have reviewed in the context of this case and presented in this report, it is my opinion that SIS is not a remanufacturer, as that term is defined by FDA, and that the company acted reasonably in its effort to conform with all applicable FDA medical device requirements. Furthermore, any suggestion that SIS's planned commercial activities, with respect to Intuitive Surgical's EndoWrist instruments, are contrary to the FDCA and will cause customers to violate the law, is false and misleading."

Lazerow Dec. Ex. 1 at "Conclusion", p. 42-43.

In opposing Mr. Phillips' analysis, Intuitive boldly and overreachingly asserts that "the FDA views the activity of modifying EndoWrists to extend the number of uses as remanufacturing requiring FDA clearance." Dkt. 121 at p. 6. However, the particular "FDA views" that Intuitive references are only the non-public and non-binding assertions of low level FDA employees. Lazerow Dec. Ex. 5 at ¶ 28. Those employees do not have any delegated legal authority to render a final, policy decision binding on the entire FDA and the public as to particular regulatory issues.[1, 2]

Intuitive asserts, incorrectly, that Mr. Phillips "conceded that he has not seen a single statement by anyone at FDA that agrees with him that the activity at issue in this case

[1] The Staff Manual Guide (SMG) sets forth the Food and Drug Administration's (FDA) policy and procedures governing Regulatory and Administrative Delegations of Authority (DOA). Delegations of Authority are the formal assignment or commitment of legal power, usually to subordinate officials, to make certain decisions and take certain actions that have legal significance. It may involve regulatory authority, administrative authority, or both. DOAs are required for the performance of such functions as: 1. Regulating non-government activities. SMG 1401.1, p. 2 at Section 4.A.1. (2011).

[2] Intuitive asked Mr. Phillips to assume at his deposition "that every single FDA official who has communicated with anyone in industry stated that the activity is remanufacturing," but Intuitive's counsel acknowledged that his hypothetical did not include the Commissioner of the FDA. Lazerow Dec. Ex. 2 at 159:13-17. Thereafter, Mr. Phillips responded to the questions about the content of hypothetical communications from or letters written by hypothetical FDA officials that "there's a chance the individuals could be wrong." Lazerow Dec. Ex. 2 at 159:23-24.

does not constitute remanufacturing." Dkt. 121 at p. 6[3] (citing to an excerpt from Mr. Phillips' deposition)). What Mr. Phillips actually testified to was that he had not seen any statements that characterized the extension of the lives of an EndoWrist as "servicing" or "repair". Lazerow Dec. Ex. 2 at 47:10-24.

Intuitive argues that Mr. Phillips' opinion "violates Rule 702 because it is an *ipse dixit* conclusion not based on the facts of this case." Dkt. 121 at p. 10. Citing to a page from Mr. Phillips' deposition, Intuitive claims that he "is equally adamant that he is uniquely and 'definitively' able to distinguish remanufacturing from servicing in this case; he says there is no 'doubt in [his] mind whatsoever' that SIS is not a remanufacturer." Id. (citing Lazerow Dec. Ex. 2 at 409:4-20). Intuitive's self-serving "cherry-picking" from Mr. Phillips' deposition distorts and mischaracterizes Mr. Phillips' analysis of the "remanufacturing" question relative to SIS's activities. Mr. Phillips testified that he does not believe that the definition of "remanufacturer" in the QSR is clear and that the FDA admitted that fact. Lazerow Dec. Ex. 2 at 409:4-9. Further, Mr. Phillips testified that it's his opinion that SIS's activities were not remanufacturing as currently defined and that he's come to that conclusion definitively with zero doubt in his mind. Id. at 409:10-20.

Faced with this clear testimony, Intuitive argues that "what efforts SIS actually undertook to conform to those requirements . . . is literally the stated reason for [Phillips'] retention and the subject matter of his principal opinion." Dkt. 121 at p. 8. But this misstates the issue addressed by Mr. Phillips – the issue is not the specific "efforts that SIS *undertook to understand the applicable FDA regulatory requirement*" (Lazerow Dec. Ex. 2 at 223:21-224:16 (emphasis added)) but rather, whether SIS was objectively reasonable in not seeking FDA approval *in view of the underlying activities it performed and intended to perform* for EndoWrists. His opinion addresses this issue in detail.[4] Lazerow Dec. Ex. 1 at

[3] References to Intuitive's Motion are to the docket entry of the publicly filed brief and the page number within the brief, while references to exhibits attached to the Motion reference the exhibit numbers of the Lazerow declaration available at Dkt. 121-1. The under-seal Motion and exhibits are available at Dkt. 130-38-48, with Dkt. 130-39 corresponding to Lazerow Dec. Ex. 1.

[4] Intuitive attacks Mr. Phillips' analysis alleging that he "does not explain how the specific modifications that SIS and Rebotix made to EndoWrists relate to the regulatory

¶¶ 76-92 (Mr. Phillips discussing specific activities SIS performs for EndoWrist repair); Id. at ¶¶ 100-114 (Mr. Phillips applying those facts to the existing FDA regulatory framework).

Assessing the relevance of Mr. Phillips' opinions requires applying the standard required by Fed.R.Evid. 702 and *Daubert.* "[R]elevance means that the evidence will assist the trier of fact to understand or determine a fact in issue." *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007). Relevancy simply requires that the evidence logically advance a material aspect of the party's case. *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188 (9th Cir. 2019). Here, Intuitive has raised the issue – despite FDA's non-enforcement of "remanufacturing" regulations and failure to even finalize guidance defining a "substantial change" after 20+ years of trying – of whether SIS was reasonable in not requesting 510(k) approval.[5] Mr. Phillips testimony is directly relevant to this issue. He is not attempting to decide the ultimate issue (which FDA may someday decide), but to assist the Court and jury in understanding that SIS's activities fall firmly in the region where FDA has explicitly failed to provide guidance.

B. Intuitive's FDA expert undertakes the same analysis as Mr. Phillips regarding "remanufacturing".

Intuitive challenges the admissibility of Mr. Phillips' opinion that SIS cannot be definitively considered a "remanufacturer" by first asserting his opinion is a legal conclusion. Intuitive claims "Phillips is offering to tell the jury how he thinks the FDA's

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requirements." Dkt. 121 at p. 8. That is simply not true. Mr. Phillips agrees that determining whether servicing or repair activities amount to "remanufacturing" a medical device focuses on how those activities have changed the device, if at all. That is, whether the finished device, as a result of being serviced or repaired, has been "significantly" changed in terms of "performance or safety specifications, or intended use." Lazerow Dec. Ex. 1 at ¶¶ 56, 68. Thus the central issue is the objective reasonableness of SIS's decision to engage in its commercial activities without FDA 510(k) clearance in the context of what changes were being made to the EndoWrist during the servicing operation. *See* Lazerow Dec. Ex. 1 at ¶¶ 98, 100, 108. To that end, Mr. Phillips interviewed SIS's President/CEO, Greg Posdal, about the details of how SIS's services repaired EndoWrists. Lazerow Dec. Ex. 1 ¶¶ 76-98. Based upon that information, combined with other evidence of record, Mr. Phillips opines that SIS's decision to engage in EndoWrist repair servicing without FDA clearance was reasonable. Id. at ¶ 4i-ii, 100-114.

[5] Intuitive's argument appears premised on the notion that in every case, before a company engages in any activities related to a medical device, it must independently consider whether FDA regulatory clearance is necessary and failure to do so renders the company's actions per se objectively unreasonable.

legal regime applies to the facts of this case, substituting his own personal conclusions for those of the agency." Dkt. 121 at p. 9. Neither aspect of Intuitive's criticism of Mr. Phillips' opinion is valid.

Mr. Phillips is not offering to tell the jury how he thinks the FDA regulatory definitions apply to the facts of this case. His expert testimony offers his opinion that relying on the FDA's regulatory definitions regarding "remanufacturing", it is not possible to reach a definitive legal determination, one way or the other, as to SIS's EndoWrist service operation. Intuitive's FDA expert, Ms. Christy Foreman, reaches a different conclusion in her expert report after having conducted essentially the same analysis of the FDA regulations related to "remanufacturing". Lazerow Dec. Ex. 4 at ¶¶ 16(b)(iv) 1 and 2, 67-74, and 164-179. In paragraph 200 of her report, Ms. Foreman states:

> "What the third parties do is in fact remanufacturing. There is no ambiguity on this point, and Intuitive was correct in its belief that the third parties' activities violated FDA regulations. Moreover, SIS's decision to engage in these activities without 510(k) clearance was unreasonable.
>
> * * *
>
> Because the third parties were remanufacturing EndoWrist instruments, a 510(k) clearance was required, and SIS's decision to not pursue 510(k) clearance for these activities had no basis in a reasonable interpretation of the law."

Lazerow Dec. Ex. 4 at ¶ 200-201, 216 and 270.

The FDA actually has not made a final, legally binding determination that modifying EndoWrists to reset their use counters is "remanufacturing" activity that requires 510(k) clearance. It is Intuitive's FDA expert, Christy Foreman, who opines that the FDA has made such a determination. Dkt. 121 at p. 9, n. 4; *see also* Lazerow Dec. Ex. 4 ¶ 16(b)(iii). Mr. Phillips, however, reaches the opposite conclusion and disagrees with Ms. Foreman's opinion, based on his years of experience with FDA's internal procedures and processes. Mr. Phillips is not substituting his own personal conclusions for any final, legally binding, official regulatory determination by the FDA.

In its motion to exclude Mr. Phillips' testimony, Intuitive references part of the *Daubert* rulings by the district courts overseeing the prior (and now settled) Rebotix and

Restore lawsuits against Intuitive. Dkt. 121 at p. 10. Intuitive neglects to point out to this Court that the district court in Rebotix found that the FDA had not made an official, definitive and final determination regarding whether resetting the EndoWrist use counter constituted "remanufacturing" and thus required 510(k) clearance:

> "[W]ithout definitive and final guidance from the FDA, if the Court were to wade into the evidence and make a determination on this point, it would necessarily be intruding upon the FDA's exclusive area of authority and usurping the FDA's authority to enforce the FDCA. * * * For the reasons stated above, the Court will not at this juncture issue a determination with respect to whether or not Rebotix's services and/or products require Section 510(k) clearance. It will not address the related question of whether Rebotix's services constitute "remanufacturing." Such questions are for the FDA to determine in the first instance. There does exist the possibility, however, that the FDA could issue an official and final determination between now and the time of trial."

Rebotix Repair LLC v. Intuitive Surgical, Inc., 8:20-cv-2274-VMC-TGW, at pp. 16-18 (M.D. Fla. Aug. 10, 2022).[6]

C. The non-public communications and actions by FDA employees, cited by Intuitive, do not constitute official FDA policy and have no binding legal authority with respect to the agency or the public generally.

It is undisputed that the FDA has not actively prohibited SIS, Rebotix or Restore from conducting service operations where the use counter is reset for EndoWrist surgical instruments. Moreover, FDA has knowingly continued to permit such operations without 510(k) clearance.

Nevertheless, Intuitive challenges the admissibility of Mr. Phillips' opinions on the basis that he "did not even consider, much less take account of, the extensive record that FDA has itself made on this subject [of remanufacturing]." Dkt. 121 at p. 10. However, the "record" that Intuitive cites to support its argument consists of either language used by other parties in non-public communications to the FDA or FDA's non-public, confidential

[6] The Rebotix court also stated: "Therefore, the Court will not, at this time, grant summary judgment on Intuitive's counterclaims to the extent they are based on allegations that Rebotix does not comply with FDA regulations. If, however, the FDA has not issued an official, final determination on this issue on the eve of trial, the Court invites Rebotix to renew its motion for summary judgment as to these counterclaims and the Court will grant summary judgment at that time." *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, 8:20-cv-2274-VMC-TGW, at pp. 18-19 (M.D. Fla. Aug. 10, 2022).

communications to private parties, including informal email exchanges. Dkt 121 at p. 10-11 (citing Lazerow Dec. Exs. 8, 9, 10 at BPI000335, 11 at Intuitive-00706024, Intuitive-00706038, and Intuitive-00706073, 13 at AHP000534-35, 14 at REBOTIX175727, REBOTIX175712)). Nothing in the "record" relied upon by Intuitive is legally binding on the agency as a whole or the public at large. Nothing in the cited "record" constitutes an official, public statement of the FDA's final policy or regulatory determination that activities where the servicing of an EndoWrist instrument involves resetting the device's use counter constitutes "remanufacturing".

Intuitive derides Mr. Phillips for not having addressed in his rebuttal report any of the emails etc. comprising the so-called "record that the FDA made" on the subject of resetting the EndoWrist use counter. Dkt. 121 at p. 11, n. 5. Intuitive then attempts to belittle Mr. Phillips' analysis with the characterization that "at deposition, Phillips clung to the idea that statements by some of the individual FDA officials do not 'necessarily represent the opinion of FDA.'" Lazerow Dec. Ex. 2 at 337:21-338:17." Id.

At his deposition, Mr. Phillips clearly and directly stated: "but Dr. Lee doesn't have the authority to take any significant actions by way of a simple email." Lazerow Dec. Ex. 2 at 338:3-5. Mr. Phillips continued: "Well, he [Mr. Lee] can believe whatever he wants, but he doesn't necessarily represent the opinion of the FDA. He may suggest that that's the case, but by corresponding informally by way of an email, that is not an appropriate way for the FDA to cause any regulated entity to take any kind of a significant action." Id. at 338:9-17.[7]

Intuitive's FDA expert, Christy Foreman, discusses many of the emails etc. that are included in Intuitive's so-called "record that the FDA made" relating to EndoWrists. Lazerow Dec. Ex. 4 at ¶¶ 103-136, 139-142. In fact, Ms. Foreman credits those informal, non-public communications involving FDA employees and third parties with great

[7] Intuitive complains that "Phillips never defines what he views as the 'opinion of FDA' or otherwise identifies the evidence he would want to see to ascertain the 'opinion of FDA.' " (Dkt. 121 at 11, n. 5). But Intuitive choose not to ask Mr. Phillips those questions during his seven-hour deposition in this case.

significance. Lazerow Dec. Ex. 4 at ¶ 217, 221-226. However, Ms. Foreman does not assert in her report that any of those documents constitute official FDA policy or a final determination on the issue that has binding legal authority with respect to the agency as a whole or the public generally. *See* Lazerow Dec. Ex. 4 at ¶233-235.

In contrast to the position taken by Intuitive's expert, Mr. Phillips' opines:

> "Although there is no FDA guidance in effect on what constitutes a 'significant change' and is therefore 'remanufacturing,' as is the case with OEMs making changes to their legally marketed devices, the responsibility for determining whether a particular change rises to a level of significance that requires the submission of a 510(k) rests with the person affecting the change. Once the modified device becomes available, it is up to FDA to disagree and require a 510(k). With an FDA guidance document in effect, there may be suggested ways of assessing significance, but without an FDA guidance document in effect, industry is left to interpret that regulations and do what seems reasonable."

Lazerow Dec. Ex. 1 at ¶ 66.

Even official "guidance" documents issued by the FDA have no legally binding effect on the agency or the industry. *See* Lazerow Dec. Ex. 4 at ¶¶ 24-25. Clearly then, the actions of an FDA employee without officially delegated authority to bind the agency cannot bind other employees, cannot bind the Agency as a whole, do not represent an official FDA policy determination or final decision, and cannot have any legally binding effect on the public, including SIS. *See* Lazerow Dec. Ex. 4 at ¶ 233.

II. Submission of a 510(k) and obtaining an FDA clearance by others does not establish that either is in fact, necessary or required for SIS's repair services.

Intuitive is attempting to take the position that a third party's voluntary decision to pursue 510(k) approval (which FDA granted) means that all EndoWrist repair processes require FDA approval. In this instance, a third party gained FDA approval for a process that included similar functional steps of resetting and repairing the EndoWrists, but also included repackaging and relabeling for delivery and distribution into the open market. As discussed below, Mr. Phillips' opinion as to the significance (or lack thereof) of this voluntary effort under FDA regulations and practices is proper, relevant and admissible.

Intuitive challenges the admissibility of Mr. Phillips' opinion and his independent assessment of SIS's decision to proceed with its EndoWrist repair service without FDA 510(k) clearance on the basis that "he does not know whether Iconocare's activity constitutes remanufacturing because he has not seen the content of its 510(k) application." Dkt. 121 at p. 7. However, knowing the "details of the activity" Iconocare performed or that FDA assessed is unimportant and unnecessary for the purposes of Mr. Phillips' objective analysis. Likewise, whether or not one or two FDA employees referred to Iconocare's activities in modifying Endo Wrists as "remanufacturing" is beside the point in the context of the issue being addressed by Mr. Phillips. Indeed, Mr. Phillips opines that "[t]he submission of a 510(k) and an FDA clearance by others does not establish that either is in fact necessary or required for SIS's repair services." Lazerow Dec. Ex. 1 at ¶¶ 117-122.

Intuitive continues its unjustified attack on Mr. Phillips' credibility by charging that he "did not consider (or even know about) the fact that, in conjunction with clearance of Iconocare's 510(k) for remanufacturing a Si EndoWrist, the FDA [through a request by a low level employee] created a new 'product code' for a 'computer controlled instrument' that has been 'remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.' " Dkt. 121 at p. 6. The cited excerpt from Mr. Phillips' deposition does not support Intuitive's allegation. Mr. Phillips acknowledged that he had not seen the new product code when he wrote his opening report. Lazerow Dec. Ex. 2 at 36:15-21. Tellingly, Intuitive neglects to advise the Court that Mr. Phillips specifically addresses this product code argument in his expert rebuttal report. Lazerow Dec. Ex. 5 at ¶¶ 31-32. Mr. Phillips offers the following analysis in that report of Intuitive's product code argument:

> "The fact that the 'QSM' product code was created for a device cleared as a remanufactured NAY instrument and refers to a 'System, Surgical, Computer Controlled Instrument, Remanufactured', is not evidence of an FDA determination that the activities described in the 510(k) submission constitute remanufacturing as opposed to servicing. As stated in my Opening Report, clearance of such a 510(k) results in a classification decision that subjects the 510(k) submitter to the applicable regulatory controls of the FDCA. The decision does not establish

> that the submitter significantly changed the device and is a remanufacturer, nor does it prohibit the submitter from engaging in any servicing activities."

Id. at ¶ 31.

Based on these misstatements, Intuitive argues that Mr. Phillips' "opinion about Iconocare's status is a legal conclusion not helpful to the trier of fact." Dkt. 121 at p. 12. However, Intuitive wishes to wave the voluntary, unprompted, 510(k) of a third party in front of the jury as evidence that that other parties such as SIS are necessarily required to seek 510(k) approval. Mr. Phillips' opinion properly puts the voluntary nature of the Iconocare 510(k) in context (Lazerow Dec. Ex. 1 at ¶¶ 117-18, 120-21), addresses the regulatory (non) significance of product code assignment (*see supra*), and relevant differences between the Iconocare approval and SIS business model from an FDA perspective (Lazerow Dec. Ex. 1 at ¶ 121). This testimony is proper, relevant and admissible.

An expert can testify based on his knowledge and experience. *See United States v. Holguin*, 51 F.4th 841, 855 (9th Cir. 2022) ("The Rules Advisory Committee has explicitly recognized that 'the application of extensive experience' is a 'method' that can reliably support expert testimony."). Through the application of his extensive experience, Mr. Phillips analyzed the case of Iconocare's modified Si EndoWrist and the FDA's clearance of the 510(k) submission to the extent such information was publicly available. Lazerow Dec. Ex. 1 at ¶¶ 120-121. As Mr. Phillips points out, FDA found the device with the extended life (i.e., an additional 10 uses) was substantially equivalent (SE) rather than not substantially equivalent (NSE) to the legally marketed predicate devices.

Notwithstanding the questionable assigned product codes "QSM" and "NAY",[8] Mr. Phillips opines that the only reasonable inference that can be drawn is that Iconocare Health's device, referred to as "8mm Monopolar Curved Scissors", has the same intended

[8] It would appear, based on the product code guidance Intuitive references, that the assignment of the new codes to Iconocare's device was a mistake or at least not warranted. A new product code is supposed to be assigned only when the proposed device is found not substantially equivalent (NSE). Iconocare's modified Si EndoWrist device was, however, found to be substantially equivalent (SE) to the predicate Intuitive EndoWrists devices. Lazerow Dec. Ex. 1 at ¶¶s 120-121.

use and technological characteristics as the legally marketed predicate devices with which it was compared (all manufactured by Intuitive Surgical). Lazerow Dec. Ex. 5 at ¶ 32. If there had been a change in intended use, Iconocare Health's 510(k) would not have been substantively reviewed. Id. As Mr. Phillips discusses in his report, after the substantive review, FDA's overall finding with respect to Iconocare Health's Si EndoWrist device is clearly stated in its 510(k) Summary for 510(k) K210478 as follows:

> "The design, materials, and intended use of the 8mm Monopolar Curved Scissors Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the reusable device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations."

Id.

Sidestepping FDA's language in its 510(k) Summary, Intuitive overplays and exaggerates the significance of the new product code with respect to Iconocare Health's cleared Si EndoWrist device. As Mr. Phillips points out in his rebuttal report:

> "Product codes are used in identifying and tracking devices, or premarket submissions, associated with attributes or characteristics of interest, however, establishing a product code is nothing more than a simple administrative action taken most often at the lowest levels of the Agency. Rarely do higher level employees request that a new product code be established. Typically, the lead reviewer, or first line supervisor, requests issuance of a new product code to be assigned to a device when a final decision on a premarket submission is made and someone recognizes a need to create an ability to search the FDA database for certain submissions or devices with certain attributes."

Id. ¶ 31. Mr. Phillips testimony in this regard is both proper and helpful to the jury.

III. Mr. Phillips' opinion that Intuitive's customer communications were false and misleading is admissible evidence.

Intuitive does not contest the accuracy of the statements made in SIS's complaint on which Mr. Phillips relies for his opinions. Intuitive does not contest the accuracy of the cited quotations from its own documents and customer communications. On that basis, Mr.

Phillips opines that Intuitive's customer communications were false and misleading. Lazerow Dec. Ex. 1 at ¶¶ 99, 123-125.

Intuitive admits that it shared with customers the view that FDA clearance is needed to reset the EndoWrist use counter, and contends that such statements were "completely accurate." Dkt. 121 at p. 3. Indeed, Intuitive's FDA expert, Christy Foreman, states in her report: "I understand that Intuitive told customers and FDA that the activities of these third parties were remanufacturing EndoWrist instruments in violation of FDA regulations and guidance." Lazerow Dec. Ex. 4 at ¶ 255.

Intuitive communicated to customers directly and implicitly that SIS definitely needed FDA clearance to conduct its EndoWrist operations legally. That allegation, however, is a false statement because the facts show that the FDA has made no such determination and hasn't even established definitions necessary to make that determination. At best, there is uncertainty and ambiguity about FDA regulations on the subject. Accordingly, an objectively reasonable (and responsible) company would have accounted for such uncertainty in communicating to customers and thus avoid making a definitive statement essentially charging SIS with illegal conduct in violation of FDA regulations. Any alleged flaws in Mr. Phillips' analysis of Intuitive's customer communications can be adequately addressed through cross-examination at trial, rather than exclusion.

CONCLUSION

For all of the reasons stated above, SIS respectfully requests that the Court deny Intuitive's motion to exclude all of Mr. Phillips' opinions in this matter.

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